DIA Training Course

Advanced GCP Study Monitoring

Course #13549
05-06 June 2013
Basel, Switzerland

Faculty / Instructor

Angelika Karwoth
Senior Clinical Research Consultant
Angelika Karwoth GmbH, Germany

Jennifer Kealy, BSc MPH
Managing Director
Cascade Clinical Consulting, France

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.
The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.
DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.
For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.
The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 6.5 credits.

This course has limited capacity. Register early.

Overview

Clinical research monitors perform a critical role in the conduct of a clinical trial. As the primary liaison between the sponsor and the site, the monitor must verify that the clinical trial is conducted according to Good Clinical Practice (GCP), the safety and rights of subjects are protected, the Investigational Medicinal Product (IMP) is handled correctly and the data is of the highest quality. This course will expand and strengthen the monitoring skills of Clinical Research Associates (CRAs), enabling them to perform their role more proficiently and effectively.
Using case studies, monitors will learn how to handle monitoring problems and proactively manage risks before they become audit findings later. This course includes an invaluable "shared experience session" which will enable colleagues to discuss monitoring challenges they face as well as a risk-based monitoring plan workshop.

Key Topics

- Research misconduct
- Risk management for the monitor
- Elements of Corrective and Preventive Action Plans (CAPA)
- Advanced monitoring techniques and tools
- Benchmarking for site performance evaluation
- Source document/data evaluation
- Electronic source data verification
- Risk-based monitoring plans

Who Will Attend

- Pharmaceutical, biotechnology and medical device industry employees
- Freelancers, consultants
- CRAs with a minimum of 2-3 years work experience who want to acquire advanced monitoring skills
- Experienced CRAs
- Clinical Managers
- Contract Research Organisations
- Study coordinators, interested in monitoring from the sponsor's perspective

Course Level

Intermediate – Advanced

Learning Objectives

At the conclusion of this course, participants should be able to:

- Describe the role and responsibilities of the monitor
- Evaluate source documents and electronic records competently
- Identify signs that suggest potential misconduct and fraud
- Manage monitoring risks proactively
- Apply Root Cause Analysis (RCA) techniques when uncovering site problems
- Develop effective Corrective and Preventive Action Plans (CAPA)
- Assess the success of corrective action through benchmarkings
- Describe risk-based monitoring approaches
- Develop a risk-based monitoring plan

PharmaTrain recognised
PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DIA®
www.diahome.org

WEDNESDAY | 05 JUNE 2013

12:00 **REGISTRATION**

12.30 **WELCOME AND INTRODUCTION**

Role and Responsibilities of the Monitor

13:00 **Session 1**

RESEARCH MISCONDUCT AND FRAUD: IDENTIFYING THE RISKS

Sadly, research misconduct or fraud is more common than you might think. As an experienced monitor you will probably have encountered it, possibly without realising it. This session will help you learn how to detect research misconduct and, when you have, what you should do about it.

15:00 **COFFEE BREAK**

15:15 **Session 2**

ROOT CAUSE ANALYSIS AND CORRECTIVE ACTION PLANS

Monitors are often confronted with a variety of problems during a clinical trial, including protocol non-compliance, issues with IMP handling and staff performance, to name a few. Many situations are avoidable, if identified and addressed early. Learn how to systematically assess risks and uncover real cause(s) of problems identified during monitoring visits, using Root Cause Analysis. By knowing the cause of the problem, you can then formulate an effective Corrective and Preventive Action Plan. Proactively manage risks in your study before it is too late.

17:15 **RECEPTION**

18:15 **END OF DAY ONE**

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Dorint an der Messe Basel Hotel
Schönaustrasse 10
4058 Basel
Switzerland
Email: info.basel@dorint.com
Tel: 0041 61 695 70 00
Fax: 0041 61 695 71 00
Website: www.dorint.com/basel

at the rate of:
CHF 230.00 per standard room, single occupancy inclusive of breakfast buffet, VAT & mobility ticket.

To make your reservation please use this booking form available on the DIA website.

IMPORTANT: Please complete your reservation by 06.05.2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

CANCELLATION: Cancellations of reservations are possible until +31 days prior to arrival. No shows will be billed for the entire stay.

THURSDAY | 06 JUNE 2013

09:00 **Session 3**

SOURCE DOCUMENT EVALUATION

Good source documents are vital if you are to be able to prove the integrity of your site's study data to auditors and GCP inspectors. This session will refresh your memory on the basics of source data and provide you with tools to assist you in evaluating and monitoring both paper and electronic records.

10:00 **Session 4 Interactive Session**

WHAT ARE THE COMMON MONITORING PROBLEMS? SOLUTIONS?

Bring your questions and challenges that you face in your role as a monitor. This is a unique opportunity to share experiences and learn from other monitors.

10:45 **COFFEE BREAK**

11:00 **Session 5**

ADVANCED MONITORING TECHNIQUES AND TOOLS/ BENCHMARKING IMPROVEMENT

All too often, monitors get caught up in the details when performing Source Data Verification and fail to identify important trends and emerging risks that can lead to serious problems. Learn the common techniques GCP auditors use that can be applied during monitoring visits to identify trends early in a trial. The concept of benchmarking will be introduced as a way to assess site performance and improvement.

12:30 **LUNCH**

13:30 **Session 6**

RISK-BASED MONITORING PLANS

Not all trials run the same risk of non-compliance with GCP. The risk depends on a variety of factors, including, but not limited to, the IMP, protocol complexity, trial endpoints and experience of site staff. How can we determine the right amount of quality management necessary for a specific trial? Learn the key factors to consider for a risk-based monitoring plan, based on the 2011 EMA reflection paper on risk based quality management and the FDA draft guidance on a risk based approach to monitoring.

14:30 **Session 7**

WORKSHOP, DEVELOP A RISK BASED MONITORING PLAN

(Coffee/tea available while participants are in their working groups)

16:00 **WRAP UP**

16:30 **END OF TRAINING COURSE**

REGISTRATION FORM

DIA Training Course: Advanced GCP Study Monitoring
05-06 June 2013 I Basel, Switzerland

DIA www.diahome.org

ID #13549

FEES

		Member*	Non-Member*
Industry	€	1'155.00 ❑	€ 1'270.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€	578.00 ❑	€ 693.00 ❑
Join DIA now to qualify for the member rate	€	115.00 ❑	

*All fees will be subject to the Swiss VAT at 8 %

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Registration fee includes: refreshments, lunches and training course material

TOTAL AMOUNT DUE: _____

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #13549 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.
- Tutorial cancellation: € 50.00.

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland